APR 15 2013

510(K) SUMMARY

Corentec Co., Ltd.

LOSPA TKR System – Spec Inclusion

5nd March, 2013

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	LOSPA TKR System
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Regulations:	21 CFR 888.3560
Class:	II
Product Codes:	JWH
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The intended use of the added specification has not changed as a result of the modification of the predicate device cleared under Lospa Total Knee System, K110404 & K121037.

The Lospa Total Knee Replacement System is intended for use in total knee arthroplasty surgery for the following indications:

- Painful, disabling joint disease of the knee resulting from non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure.

The LOSPA Total Knee Replacement System is intended for cemented use only.

DEVICE DESCRIPTION

The LOSPA TKR System specification inclusions are components of "LOSPA Total Knee System" cleared under K110404 & K121037 which consists of Femoral Components, Tibial Base plate, Tibial Insert, Patellar Components and Instrumentation – LOSPA Total Knee Instrumentation for use with the system implant components.

Femoral Components

Femoral components are available in CR and PS designs. There are five additional sizes, #6, 8#, #12, #14 & #16 of each design (CR and PS), each for left and right sides. For both the CR and PS designs, the ranges of dimensions are the same. All femoral components are manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F75, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).

Tibial Base plate

The tibial base plate, are made available in additional sizes, #6, 8#, #14 & #16, to provide optimal tibial coverage. The tibial base plates are designed for use in either the left or right side, and with either CR or PS femoral components and corresponding tibial inserts. All tibial base plate components are manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F75, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).

Tibial Inserts

Additional size tibial inserts corresponding to tibial base plate, are made available in sizes, #6, #13, #14 & #16, to provide optimal tibial coverage. Tibial inserts are available for both the CR and PS designs.

The ultra-high molecular weight polyethylene (UHMWPE) tibial inserts is provided with bearing surfaces in various thicknesses. The polyethylene used for all tibial inserts is

manufactured from UHMWPE conforming to ASTM F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants, Type 1 (GUR 1020).

Patellar Components

Patellar components cleared in K110404 are provided in two types, dome and sombrero. This submission includes only dome type. Additional sizes are included to offer a wide choice in the term of 'thickness' & 'peg distance' than existing approved specifications. The polyethylene used for all patellar components is manufactured from UHMWPE conforming to ASTM F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants, Type 1 (GUR 1020).

All sizes of the patellar components are compatible with all sizes of the femoral components. The design of the patella component is exactly same as the device cleared in K110404.

SUBSTANTIAL EQUIVALENCE

LOSPA TKR System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent, as below,

- **Corentec Co., Ltd.**, Eaum Total Knee System (*now renamed as LOSPA Total Knee System*) cleared under K110404
- **Corentec Co., Ltd.**, LOSPA Tibial Base Plate, cleared under K121037
- **Howmedica Osteonics Corp. (Stryker)** Scorpio 'NRG' Knee cleared under K030978

PERFORMANCE TESTING

Performance testing – Bench, was not required since engineering analysis showed that the inclusion of additional specification did not change the worst case configuration tested in both K110404 & K121037. Also the predicate device Scorpio 'NRG' Knee cleared under K030978 has similar specification as the additional specification included in this submission. Also the Scorpio 'NRG' Knee cleared under K030978 was used as a predicate device in LOSPA TKR System approval in both K110404 & K121037. Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy.

Overall, the LOSPA TKR System components has similarities to the predicate device/s with the same intended use, same fundamental scientific technology, same operating principles, same materials and are supplied Sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 15, 2013

Corentec Co., Ltd
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South Korea

Re: K130673
Trade/Device Name: LOSPA Total Knee Replacement System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: March 28, 2013
Received: April 2, 2013

Dear J.S. Daniel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K130673

Device Name: LOSPA Total Knee Replacement System

The Lospa Total Knee Replacement System is intended for use in total knee arthroplasty surgery for the following indications:

- Painful, disabling joint disease of the knee resulting from non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure.

The LOSPA Total Knee Replacement System is intended for cemented use only.

Prescription Use: X AND / OR Over-The Counter Use: ____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices